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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,341	11/21/2000	Jennifa Gosling	19934-000711US	5168

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EXAMINER
BUNNER, BRIDGET E

ART UNIT	PAPER NUMBER
1647	11

DATE MAILED: 08/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/721,341	GOSLING ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25 and 27-36* is/are pending in the application.

4a) Of the above claim(s) *1-24 and 28-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25 and 27-36* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendments of 01 August 2001 (Paper No. 5), 12 February 2002 (Paper No. 7), and 28 May 2002 (Paper No. 10) have been entered in full. Claims 25 and 32 are amended and claim 26 is cancelled.

Election/Restrictions

Applicant's election with traverse of Group VII, claims 25-27, drawn to a method of identifying a modulator of the binding of CCX CKR to a chemokine in Paper No. 10 (28 May 2002) is acknowledged. The traversal is on the ground(s) that all the current claims in Groups VII-X should be examined together because each of these groups include claims derived from the same concept and theory and thus are related. Applicant argues that all the claims in Group VII-X are drawn to methods of identifying a modulator of CCX CKR activity or to methods of formulating a modulator identified by such methods as a pharmaceutical composition. Applicant contends that all the claims in these four groups have been classified to the same class and subclass. Applicant also argues that the similarity in issues and steps involved in the claims in these four groups means that a search for art in one group will be substantially the same as a search for art in the other groups. Applicant asserts that claim 28, the sole claim in Group VIII, involves all the same steps as the method of base claim 25 in Group VII, and is no additional burden to search. This is not found persuasive. Although classified in the same class, Inventions VII-X are different methods that require different ingredients, process steps, and endpoints. Invention VII requires search and consideration of contacting an isolated CCX CKR polypeptide and a chemokine in the presence of a test compound and comparing the *level of binding* of the

chemokine and polypeptide with the level of binding in the absence of the test compound. Invention VIII requires search and consideration of formulating a modulator for pharmaceutical use. Invention IX requires search and consideration of contacting a cell expressing a recombinant polypeptide and a test compound and assaying for a *biological effect* that occurs in the presence but not in the absence of the test compound, which is not required by the other inventions. Invention X requires search and consideration of formulating a modulator of CCX CKR activity for pharmaceutical use. Additionally, claim 28 in Invention VIII is specific in that it is directed to purifying or formulating a modulator for pharmaceutical use. Claim 25 is only directed to identifying a modulator. Therefore, Invention VIII requires additional steps that are not necessary in Invention VII. Applicant's election with traverse of the species of chemokine (mMIP-1γ) in Paper No. 10 (28 May 2002) is acknowledged. The traversal is on the grounds that there are only 7 disclosed species in claim 25 and that these species are closely related in that they are all chemokines. Applicant contends that the examination of claim 25 in its entirety can be made without undue burden. This is not found persuasive. As discussed in the specification of the instant application, "chemokines are a class of cytokines that play important roles in inflammatory responses, leukocyte trafficking, angiogenesis, and other biological processes related to migration and activation of cells" (pg 1, lines 18-20). Therefore, each chemokine listed in claim 25 may have a different structure and function from the other chemokines. Searching all of the chemokines in claim 25 would provide an undue search burden on the examiner because of the non-coextensive nature of these searches.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-24 and 28-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected groups and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10 (28 May 2002).

Claims 25 and 27 as they read upon the elected chemokine species of mMIP-1γ are under consideration in the instant application.

Drawings

1. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Specification

2. The disclosure is objected to because of the following informalities:

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. (See pg 13, line 31; pg 51, lines 23-24; pg 53, line 22) Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: "METHOD FOR IDENTIFYING A MODULATOR OF THE BINDING OF CCX CKR POLYPEPTIDE TO A CHEMOKINE".

Appropriate correction is required.

Claim Objections

5. Claim 25 is objected to because of the following informalities:

Claim 25 recites non-elected species of chemokines.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 25 and 27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Specifically, claims 25 and 27 recite a method for identifying a modulator of the binding of CCX CKR polypeptide to a chemokine comprising (a) contacting an isolated CCX CKR polypeptide and the chemokine in the presence of a test compound and (b) comparing the level of binding of the chemokine and the polypeptide in (a) with the level of binding in the absence of the test compound wherein the chemokine is mMIP-1γ and a decrease in binding indicates that the test compound is an inhibitor of binding and an increase in binding indicates that the test compound is an enhancer of binding.

The specification teaches HEK293 cells stably expressing the M1 flag epitope-tagged CKR are cultured and harvested (pg 58, lines 24025). The specification also teaches that the cells are added to each well of an assay test plate containing compounds, followed by ^{125}I-MIPβ3/ELC (pg 58, lines 29-31). After incubation, the plates are harvested and control wells containing either diluent only or excess ELC are used to calculate the percent of total inhibition

of ELC binding for each set of compounds. The specification discloses that Compounds I and II inhibit the binding between ELC and CCX CKR while Compound III enhances binding (pg 59, lines 1-7). However, the specification of the instant application does not teach any examples in which a specific CCX CKR polypeptide sequence (i.e. SEQ ID NO: 2) is utilized in the methods. The specification teaches that in some embodiments, the CCX CKR polypeptide has an amino acid sequence identical or substantially identical to the amino acid sequence shown in SEQ ID NO: 2. However, the specification also discloses that "in other embodiments, the CCX CKR polypeptides are variants and mutants characterized by conservative substitutions of amino acid residues of SEQ ID NO: 2" (pg 16, lines 24-27). The polypeptide may also be full length or a fragment of the full-length protein. According to the specification, CCX CKR polypeptides may also be modified, relative to the amino acid sequence of SEQ ID NO: 2, in some manner, e.g. truncated, mutated, derivatized, or fused to other sequences...or contain insertions, deletion or substitutions of amino acid residues relative to SEQ ID NO: 2 (pg 16, lines 28-34; pg 17, line 1). Therefore, the skilled artisan cannot determine which specific CCX CKR polypeptide sequence is used in the working examples of the instant application since the definition of CCX CKR in the specification encompasses variants and fragments of full-length CCX CKR. Furthermore, the specification does not disclose the identity of any modulator of the binding of CCX CKR to a polypeptide via the claimed method. Although Example 7 at pg 59 of the specification, states that Compounds I, II, and III inhibit or enhance binding between ELC and CCX CKR, one skilled in the art cannot predict the structure or identity of those compounds. Additionally, since the specification provides no guidance regarding what sort of compounds should be screened for the desired activity other than a chemical library, the skilled artisan must resort to trial and error

experimentation to determine which class of compounds might yield one with the desired activity. Such trial and error experimentation is considered undue. There are also no methods or working examples in the instant application to indicate that any CCX CKR polypeptide and the elected species of chemokine, mMIP-1γ, are contacted in the presence of any test compound. One skilled in the art cannot predict that the CCX CKR polypeptide is capable of binding mMIP-1γ.

Due to the large quantity of experimentation necessary to determine the proper CCX CKR sequence to use in the methods, to identify a modulator of the binding of CCX CKR to a chemokine, to determine which class of test compounds should be utilized to contact CCX CKR and a chemokine, and to determine if the CCX CKR polypeptide is capable of binding the mMIP-1γ chemokine, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to the same, the complex nature of the invention, and the breadth of the claims which fail to recite limitations on the type of CCX CKR polypeptide utilized in the claimed method, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 25 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Regarding claims 25 and 27, the acronyms "CCX CKR" and "ELC, SLC, TECK, BLC, CTACK, mMIP-1γ, and vMIPII" render the claims vague and indefinite. Abbreviations should be spelled out in all independent claims for clarity.

10. Claim 25 recites the limitation "CCX CKR polypeptide" in line 3. There is insufficient antecedent basis for this limitation in the claim. (Please note that this issue could be overcome by inserting the term "polypeptide" after "CCX CKR" in line 2 of the claim.)

Conclusion

No claims are allowable.

The art made of record and not relied upon is considered pertinent to applicant's disclosure:

Gosling et al. J Immunol 164 : 2851-2856, 2000.

Townson et al. Eur J Immunol 32 : 1230-1241, 2002.

Schweickart et al. J Biol Chem 275(13) : 9550-9556, 2000.

Khoja et al. Gene 246 : 229-238, 2000.

Lal et al. U.S. Patent No. 5,932,445

Lal et al. WO 99/24463

Gonzalo et al. WO 99/52945

Ellis, C. EP 0899332

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BEB
Art Unit 1647
August 8, 2002

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER